

**REMARKS**

Claims 1-70 were originally filed in the present case. Claims 1-70 were canceled and claims 71-130 were added in a previous amendment. Claims 100, 105-109, 112, 115-120 and 122-130 were canceled, claims 131-133 were added, and claims 71, 93, 104, 110-111 and 121 were amended in a previous amendment. Claims 71-104, 110-111, 113-114, 121 and 131-133 are canceled, and claims 134-185 are added in the present amendment. Therefore, claims 134-185 are currently pending.

In the Office Action dated September 9, 2005, the Examiner has withdrawn a number of rejections from the previous Office Action. However, the Examiner reasserts a number of previous rejections and has added new rejections. The currently pending rejections are:

- 1) Claims 71-74, 76-78, 80-87, 90-95, 97-99, 101-104, 113, and 114 stand rejected under 35 U.S.C. 102(b) as being anticipated by Spitzer *et al.* (U.S. 3,912,666), hereinafter “Spitzer”;
- 2) Claims 121, and 131-133 stand rejected under 35 U.S.C. 103(a) as being obvious over Baker *et al.* (US 6,015,832), hereinafter “Baker”.
- 3) Claims 104, 110, 111, 113 and 114 stand rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Homoloa *et al.* (US 5, 961,958), hereinafter “Homola” or Hill (US 5,380,530), hereinafter “Hill”.
- 4) Claims 121 and 131-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker and Simmons *et al.* (US 5,405,602), hereinafter “Simmons”.

Each of these grounds of rejection is addressed in detail below.

**1. Spitzer Does Not Anticipate Claims 71-74, 76-78, 80-87, 90-95, 97-99, 101-104, 113, and 114**

The Federal Circuit has stated the relevant analysis for anticipation as follows:

"A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference."<sup>1</sup>

The Applicants respectfully submits that Spitzer does not teach each element of the Claims. For example, Spitzer does not teach an oil-in-water emulsion that is antimicrobial in the absence of a halogen-containing compound. In order to further the prosecution of the present case while not acquiescing to the Examiner's argument, and retaining the right to prosecute the original claims (or similar claims) in the future, the Applicants have amended claims 134, 155, 165, 182 and 183 to recite the element that the components of the emulsion (not including a halogen-containing compound) are combined under conditions such that said "oil-in-water emulsion is itself antimicrobial." Ample support for the amendment may be found in the Specification, pages 64-76 and 80-96 describing Examples 2-6 and 9-14.

In the Office Action of September 9, 2005 (page 3) the Examiner argues: "It is respectfully noted that claim 71 is a composition claim and composition (sic) that is antimicrobial is an intended use of the composition." The Applicants point out to the Examiner that combining the aforementioned elements (*i.e.*, in the absence of a halogen containing compound) under conditions such that the oil-in-water emulsion is itself antimicrobial, is not an expression of an intended use, but an element of the conditions of making the combinations and a physical property of the claimed compositions. The specification provides ample guidance for the selecting the appropriate type and amount of the recited components to achieve the claimed properties (providing a substantial number of working examples and providing general and specific guidelines). These properties are not inherent in emulsions containing the recited ingredients. The specification provides examples of emulsion having the recited ingredients that are not anti-pathogenic. Thus, simply finding

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<sup>1</sup> *Verdegaal Bros. V. Union Oil of California*, 2 USPQ2d 1051, 1053 (Fed.Cir. 1987)

the recited ingredients in a prior art reference does not imply the claimed properties. Spitzer fails to teach or suggest the claimed compositions and methods.

Clearly, Spitzer does not teach the claimed element in the absence of a halogen-containing compound. The emulsions of Spitzer are never said to be combined under conditions such that they are antimicrobial without the inclusion of additional “medicaments”. (Spitzer, Col 13, lines 21-22). In the Office Action of September 9, 2006 the Examiner explicitly acknowledges this distinction: “Spitzer incorporates medicaments such as histamines, sulfa drugs, antibiotics, hormones, vitamins, antimicrobials agents (sic) and procaine (column 13, line 22-53).” (Office Action of September 9, 2005, page 4). (Emphasis added). While the present invention may, in some embodiments, incorporate additional compounds, it does so when the oil-in-water emulsion is combined under conditions such that the oil-in-water emulsion itself is antimicrobial in the absence of added compounds.

The Applicants respectfully submit that Spitzer does not teach each and every element as set forth in the claims. In view of the above, the Applicants request that this rejection be withdrawn.

## **2. Baker Does Not Render the Claims 121, and 131-133 Obvious**

In the Office Action of September 9, 2006 the Examiner argues: “Claims 121 and 131-133 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,015,832). No arguments were presented against the rejection and the rejection is restated below.” (Page 4). The Examiner is mistaken. The Examiner is directed to the final page of the Applicant’s Response to Office Action of April 1, 2005, which contains the section reading: “**II. THE CLAIMS ARE NOT OBVIOUS**”, and “The Examiner has rejected claims 75 and 96, and claims 121 and 131-133 as allegedly being obvious over Baker. The Applicants respectfully disagree. Because the independent claims are patentable over Baker, the dependent claims are also patentable over Baker. In view of the above, the Applicants request that this rejection be withdrawn.”

A *prima facie* case of obviousness requires the Examiner to cite a reference, or a combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield

the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicant to allowance of the claims at issue.<sup>2</sup>

The Applicant asserts that Baker fails to disclose all elements of the present invention. For example, Baker does not teach or suggest, alone or in combination with the other cited references, the composition or methods of Claims 134, 155, 165, 182, and 183 comprising an oil-in-water emulsion and a halogen containing compound. In the Office Action of September 9, 2006 the Examiner expressly concedes that: "Baker's oil-in-water emulsion does not contain halogen containing compound (sic)." (Page 2).

The Applicants respectfully submit that Baker does not teach each and every element as set forth in the claims. In view of the above, the Applicants request that this rejection be withdrawn.

### 3. Homola Does Not Anticipate Claims 104, 110, 111, 113 and 114

The Federal Circuit has stated the relevant analysis for anticipation as follows:

"A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference."<sup>3</sup>

The Applicant asserts that Homola fails to disclose all elements of the claimed invention. For example, Homola does not teach an oil-in-water emulsion comprising an organic based solvent. As well, Homola does not teach an oil-in-water emulsion comprising an alcohol. The Examiner argues: "the composition (*i.e.*, Homola) is prepared with methanol or ethanol (column 19, line 50);" (Office Action September 9, 2006, page 5). (Emphasis added). The Applicant points out to the Examiner that while Homola uses an alcohol to prepare the emulsion, alcohol is explicitly not a component of Homola's emulsion. This point is clear at Homola Column 19, lines 47-54: "the barrier

<sup>2</sup> See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

<sup>3</sup> *Verdegaal Bros. V. Union Oil of California*, 2 USPQ2d 1051, 1053 (Fed.Cir. 1987).

material is first suspended or dissolved in an appropriate solvent (e.g. xylene, toluene, petroleum ether, methanol, ethanol . . . ). The transfer agent and, optionally, active agent(s) are then added and the solvent removed by, e.g., evaporation." (Emphasis added). Still further, Homola does not teach an oil-in-water emulsion wherein the discontinuous oil phase, the aqueous phase, the alcohol, the surfactant, and the organic phosphate based solvent are combined under conditions such that said oil-in-water emulsion is antimicrobial.

The Applicants respectfully submit that Homola does not teach each and every element as set forth in the claims. In view of the above, the Applicants request that this rejection be withdrawn.

#### 4. Homola Does Not Render Claims 104, 110, 111, 113 and 114 Obvious

A *prima facie* case of obviousness requires the Examiner to cite a reference, or a combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicant to allowance of the claims at issue.<sup>4</sup>

The Applicant asserts that Homola fails to disclose all elements of the claimed invention. For example, Homola does not teach an oil-in-water emulsion comprising an organic based solvent. As well, Homola does not teach an oil-in-water emulsion comprising an alcohol. The Examiner argues with regard to Homola: "the composition is prepared with methanol or ethanol (column 19, line 50);" (Office Action September 9, 2006, page 5). (Emphasis added). The Applicant points out to the Examiner that while Homola uses an alcohol to prepare the emulsion, alcohol is explicitly not a component of Homola's emulsion. This point is clear at Homola Column 19, lines 47-54: "the barrier material is first suspended or dissolved in an appropriate solvent (e.g. xylene, toluene, petroleum ether, methanol, ethanol . . . ). The transfer agent and, optionally, active agent(s) are then added and the

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<sup>4</sup> See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

solvent removed by, e.g., evaporation.” (Emphasis added). Still further, Homola does not teach an oil-in-water emulsion wherein the discontinuous oil phase, the aqueous phase, the alcohol, the surfactant, and the organic phosphate based solvent are combined under conditions such that said oil-in-water emulsion is antimicrobial.

The Applicants respectfully submit that Homola does not teach each and every element as set forth in the claims. In view of the above, the Applicants request that this rejection be withdrawn.

## **5. Hill Does Not Render Claims 104, 110, 111, 113 and 114 Obvious**

A *prima facie* case of obviousness requires the Examiner to cite a reference, or a combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicant to allowance of the claims at issue.<sup>5</sup>

The Applicant asserts that Hill fails to disclose all elements of the claimed invention. For example, as the Examiner concedes, Hill does not disclose an oil-in-water emulsion: “The formulation is an emulsion but Hill does not specifically state an oil-in-water emulsion.” (Office Action of September 9, 2006, page 6). To the contrary, the present invention specifically discloses and claims an oil-in-water emulsion. The Examiner argues: “Since the composition contains oil and aqueous medium, one of ordinary skill in the art at the time the invention was made is able to prepare an oil-in-water emulsion.” (*Ibid.*) The Examiner’s statement is conclusory, unsupported, and untrue. Hill does not disclose an aqueous phase or aqueous medium. This element has been supplied by the Examiner and not by Hill. Moreover, Hill does not disclose an organic based solvent. Nor does Hill disclose an oil-in-water emulsion wherein the discontinuous oil phase, the aqueous phase, the alcohol, the surfactant, and the organic phosphate based solvent are combined under conditions such that said oil-in-water emulsion is antimicrobial. Even if one were to prepare an emulsion from the

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<sup>5</sup> See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

materials of Hill, the Examiner has provided no evidence that such an emulsion would have the claimed properties (inherency must be proven as a matter of scientific fact—not by possibilities or probabilities). Considering that Hill provides no guidance, motivation, or suggestion as to selection of, amounts of, or formulation methods of materials to achieve the claimed properties, there is simply no teaching or suggestion of the claimed invention.

The Applicants respectfully submit that Hill does not teach each and every element as set forth in the claims. In view of the above, the Applicants request that this rejection be withdrawn.

## **6. Baker and Simmons Do Not Render Claims 121 and 131-133 Obvious**

A *prima facie* case of obviousness requires the Examiner to cite a reference, or a combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicant to allowance of the claims at issue.<sup>6</sup>

### **6.a. The Examiner’s References Do Not Provide a Suggestion or Motivation to Combine the Recited Elements**

An essential requirement for a *prima facie* case of obviousness is whether a person of ordinary skill in the art would be motivated to modify the reference to arrive at the claimed invention. The Applicant asserts that the Examiner has not met the burden of establishing a *prima facie* case of obviousness. *Prima facie* obviousness based on a combination of references requires that the prior art provide “a reason, suggestion, or motivation to lead an inventor to combine those references.”<sup>7</sup> “The range of sources available, however, does not diminish the requirement for actual evidence. That is, the

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<sup>6</sup> See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

<sup>7</sup> *Pro-Mold and Tool Co. v. Great Lakes Plastics Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996).

showing must be clear and particular. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not “evidence.”<sup>8</sup> The suggestion to combine prior art references must come from the cited references, not from the Applicant’s disclosure.<sup>9</sup>

As set forth in *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

“A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. . . . Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one “to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher.”

Most if not all inventions arise from a combination of old elements. . . . Thus, every element of a claimed invention may often be found in the prior art. . . . However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. . . . Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.”

The Examiner’s rejection does not establish the requisite suggestion in the art to combine elements disclosed in the prior art. “A rejection cannot be predicated on the mere identification . . . of individual components of claimed limitations. Rather, particular findings must be made as to the reasons the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the

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<sup>8</sup> *In re Dembiczkak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

<sup>9</sup> *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1998)

manner claimed.”<sup>10</sup> The need for a specific suggestion in the cited references is absolute: “The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions and cannot be dispensed with.”<sup>11</sup>

Contrary to legal requirement, the Examiner’s conclusory and unsupported assertion in the Office Action of September 9, 2006 (page 6) regarding the motivation of an ordinary artisan in view of Baker plus Simmons is not evidence. The Examiner does not, and cannot, point to which specific teachings in Baker plus Simmons motivate the ordinary artisan to combine the claimed elements. Rather, the Examiner’s assertion reflects the absence of evidence, and thus does not fulfill the obligation of the Patent and Trademark Office. The Examiner argues: “Both compositions of Baker and Simmons inactivate or kill bacteria spore (sic). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a combined composition of Baker and Simmons to form a third composition with the expectation that the third composition would inactivate or kill bacterial spores. The idea of combining them flows logically from their having been individually taught in the prior art.” (Office Action of September 9, 2006, pages 6-7). To the contrary, in *In re Saung Su Lee* the Court of Appeals for the Federal Circuit expressly prohibits this kind of substitution of the benefits of an invention for objective evidence of an invention’s obviousness by the Patent and Trademark Office.<sup>12</sup>

Because the Examiner has failed to establish motivation to modify Baker plus Simmons to arrive at the claimed invention, a *prima facie* case of obviousness must fail. In view of the above, the Applicant respectfully requests that the rejection be withdrawn.

**c. The Examiner’s Combinations of References Do Not Provide a Reasonable Expectation of Success**

The Examiner argues: “Therefore, it would have been obvious to one of ordinary

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<sup>10</sup> *Ecolochem*, 227 F.3d, 1361, 1375, 56 USPQ2d 1065, 1076, quoting *Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317.

<sup>11</sup> *In Re Sang Su Lee*, 277 F.3d 1338, 1341, USPQ2d 1430, 1433. (Fed. Cir. 2002).

<sup>12</sup> *Ibid.*

skill in the art at the time the invention was made to use a combined composition of Baker and Simmons to form a third composition with the expectation that the third composition would inactivate or kill bacterial spores." (Office Action of September 9, 2006, page 7). To the contrary, the Examiner's combination is not sufficient for a reasonable expectation of success. Alone, or in combination, Baker plus Simmons provides no specific guidance, general guidance, or any guidance whatsoever in how to combine the elements of Baker and Simmons to arrive at the present invention.

The Examiner argues "It is *prima facie* obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)." (Office Action of September 9, 2006, page 7). The Examiner's application of *In re Kerkhoven* is flawed. Baker teaches an oil-in-water emulsion. To the contrary, Simmons teaches directly away from making the Examiner's combination *i.e.*, Simmons teaches a "Nonaqueous Cold Sterilant". Baker plus Simmons yields neither an oil-in-water emulsion, nor a nonaqueous cold sterilant. Therefore, the Examiner cannot advance any evidence in support of the contention that the artisan using the compositions of Baker plus Simmons would have had a reasonable expectation of success. Because the Examiner is not able to show that a reasonable expectation of success may be found in Baker plus Simmons, the third prong of a *prima facie* case of obviousness is defective, thus entitling the Applicants to withdrawal of this rejection.

**CONCLUSION**

All grounds of rejection of the Office Action of September 9, 2005 have been addressed and reconsideration of the application is respectfully requested. It is respectfully submitted that the Applicant's claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application the Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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